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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,791	12/22/1998	KOUJI MATSUSHIMA	350292000500	3409

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EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/02/2002 24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/202,791	Applicant(s) Matsushima et al.
	Examiner Deborah Ware	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 29, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29 and 31-44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-29 and 31-44* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 22
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-29 and 31-44 are presented for examination on the merits.

The extension of 5 months of time filed on April 15, 2002, has been received and fees charged, accordingly.

1. The request filed on April 15, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/202,791, is acceptable and a CPA has been established. An action on the CPA follows.

The Preliminary amendment filed April 15, 2002, has been received and entered. Also the Information Disclosure Statement filed April 15, 2002, has been received and the reference submitted therewith has been considered as indicated on the enclosed PTO-1449 Form. Further, the address change filed on May 29, 2002, has been received and the change appears to have been made on the record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 4-7 and 19-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from another claim in the alternative only. See MPEP § 608.01(n). However, these claims have been treated on the merits.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-29 and 31-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered vague for the recitation of "indirect causes" wherein the term may take on different meanings in the claims as to what is intended within the scope of an indirect cause. It is noted that Applicants may define in the specification and provide limitations in the claims as to what constitutes such causes, but the term remains vague since direct causes may be encompassed by the injuries of which Applicants set forth in the claims to be an indirect cause of lung injury. The term is vague and further explanation on the record is requested or use of a better identifying term in the claims for defining acute lung injury or perhaps further limiting the independent claims to specific lung injuries for which are intended to be encompassed by the claimed invention.

5. Claims 1-15 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Folkesson et al., cited of record.

Applicant's arguments filed April 15, 2002, have been fully considered but they are not persuasive. The argument regarding Folkesson et al. not teaching hypoxemia is noted, however, the claims which are rejected are directed to product claims of which the intended use thereof, is not necessarily given patentable weight since Folkesson et al. clearly teach the identical anti-IL-8 antibody for treating acute lung injury. The product claims must stand on their own merit with regard to whether they are patentably distinguishable over the cited prior art.. The anti-IL-8 as

disclosed by Folkesson et al. is clearly taught to be a therapeutic agent. Thus, whether its intended use is hypoxemia or some other acute lung injury is irrelevant to these claims drawn to a product. In the alternative, the claims are at least prima facie obvious for reasons of record and as for those reasons set forth above.

6. Claims 16-29 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folkesson et al., cited of record, in view of **newly cited** Slotman cited on the enclosed PTO-892 Form, note that the date relied upon is at least March 8, 1996 but dates as far back to May 6, 1994.

Claims are drawn to processes for production of a therapeutic agent and treatment of hypoxemia in acute lung injury resulting from indirect causes of which encompasses a list of lung injuries including sepsis.

Folkesson et al. teach that IL-8 is critical for development of lung injury, note the abstract. Furthermore, in the abstract it is disclosed that neutralization of IL-8 may provide a useful therapeutical treatment for acute lung injury. The active ingredient of the therapeutic agent is disclosed to be anti-IL-8 antibody, note page 107, second col. , all lines of second complete paragraph.

Slotman teaches treatment of hypoxemia in acute lung injury resulting from indirect causes (i.e. sepsis, adult respiratory distress syndrome, systemic inflammatory response syndrome, etc.) and furthermore teaches that IL-8 is an inflammatory mediator. Note col. 1, lines 10-30 and col. 2, lines 25-30.

The claims differ from Folkesson et al. in that acute lung injury may not be resulting from indirect causes such as from a systemic inflammatory response, or sepsis for example.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to combine the teachings of Folkesson and Slotman in order to provide for anti-IL-8 antibody as an active ingredient for production of a therapeutic agent for treatment of hypoxemia in acute lung injury resulting from indirect causes. Slotman clearly teach that IL-8 is a mediator of lung injury and it would have been obvious to administer to a patient in need anti-IL-8 antibody to neutralize the IL-8 effects as the same is disclosed by Folkesson et al. Further, to treat various lung injury resulting from indirect causes would have been an obvious modification of the cited prior art. Note col. 6, all lines. In addition, to select for variations of the antibody, such as a monoclonal antibody is clearly within the purview of an ordinary artisan. The claims are rendered prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

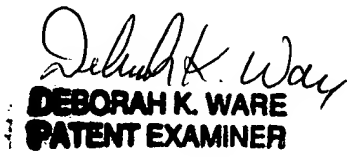
The remaining reference listed on the enclosed PTO-892 and/or PTO-1449 is cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Deborah K. Ware

Art Unit 1651

June 29, 2002